K041688

Special 510(k) Premarket Notification GE Voluson 730 Expert/Pro BT04 Ultrasound June 18, 2004

Attachment B:

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).



GE Healthcare

General Electric Company P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC

PO Box 414

Milwaukee, WI 53201

Contact Person: Allen Schuh,

Manager, Safety and Regulatory Engineering Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: June 18, 2004

2. Device Name: Voluson 730 Pro/Expert Diagnostic Ultrasound System BT04

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: Voluson 730 Pro/Expert Diagnostic Ultrasound System K003525, K032620

A device currently in commercial distribution.

- 4. <u>Device Description</u>: The Voluson 730 Pro/Expert are full featured, general purpose diagnostic ultrasound systems. They consists of a mobile console approximately 68 cm wide, 100 cm deep and 145 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, color LCD display (Expert) and color CRT. This modification will provide users with additional probe options, improved user interface and image enhancement.
- 5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal/GYN (including infertility monitoring of follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transvaginal (TV); Transrectal (TR); and Intraoperative (abdominal, PV and neurological).
- 6. <u>Comparison with Predicate Device</u>: The Voluson 730 Pro/Expert BT04 is of a comparable type and substantially equivalent to the current GE Voluson 730 Pro/Expert and GE LOGIQ 9. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

Section b):

- 1. <u>Non-clinical Tests</u>: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
- 2. Clinical Tests: None required.
- 3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Voluson 730Pro/Expert BT04 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL - 8 2004

Mr. Allen Schuh
Manager, GE Ultrasound Product Safety
and Regulatory Engineering
General Electric Company
GE Medical Systems, Ultrasound
and Primary Care Diagnostics, LLC
4855 West Electric Avenue
WEST MILWAUKEE WI 53219

Re: K041688

Trade Name: GE Voluson 730 Pro/Expert Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: June 18, 2004 Received: June 24, 2004

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Voluson 730 Pro/Expert Ultrasound System, as described in your premarket notification:

Transducer Model Number

AB2-7	<u>IC5-9</u>	<u>RSP5-12</u>
AC2-5	SCW2.0	<u>RIC5-9</u>
SP4-10	PCW4.0	<u>RRE6-10</u>
SP6-12	<u>RAB2-5</u>	<u>4C-A</u>
SP10-16	<u>RAB4-8P</u>	<u>RIC5-9H</u>
PA2-5P	RAB2-5L	<u>IC5-9H</u>
PA6-8	<u>RAB4-8L</u>	<u>RNA5-9</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Maney C Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic				ļ							<u> </u>
Fetal / Obstetrics ^[7]	P	Р	P		Р	N_	P	P	P	Р	[5,6]
Abdominal ^[1]	P	_ P	P	P	Р	P	Р	Р	P_	Р	[5,6]
Pediatric	Р	Р	Р		Р_	N	Р	Р	Р	Р	[5,6]
Small Organ ^[2]	P	P	Р	_	P	N	Р	Р	Р	P	[5,6]
Neonatal Cephalic	Р	P	P	Р	Р	Р	Р	P	Р	Р	[5]
Adult Cephalic	Р	Р	Р	Р	P	P	P	Р	Р	Р	
Cardiac ^[3]	P	Р	P	P	Р	P	Р	Р	Р	P	[5]
Peripheral Vascular	P	P	Р	P	Р	N	Р	Р	Р	P	[5,6]
Musculo-skeletal Conventional	Р	Р	P	<u> </u>	Р	N	Р.	Р	Р	Р	[5,6]
Musculo-skeletal Superficial	Р	Р	P		Р	N.	P	Р	Р	Р	[5,6]
Other					ļ		<u> </u>		ļ	<u> </u>	-
Exam Type, Means of Access		<u> </u>	ļ				<u> </u>		ļ		
Transesophageal					ļ	ļ	ļ		 	<u> </u>	
Transrectal	Р	Р	Р	ļ	Р	N	P	Р	Р	P	[5,6
Transvaginal	Р	Р	Р	ļ	P	N_	P	P	P	P	[5,6
Transuretheral			ļ		ļ		ļ	<u> </u>		 	
Intraoperative	Р	P	Р		P	N_	P	Р	Р	P	
Intraoperative Neurological	Р	P	Р		P	N	P	Р	P	P	┦—
Intravascular									ļ <u> </u>	 -	
Laparoscopic					<u> </u>		1	<u> </u>	<u> </u>	<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
- [3] Cardiac is Adult and Pediatric.
- [5] 3D/4D Imaging Mode
- [6] Includes imaging of guidance of biopsy (2D/3D/4D)
- [7] Includes infertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____

Special 510(k) Premarket Notification GE Voluson 730 Expert/Pro BT04 Ultrasound June 18, 2004

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with AB2-7 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration	<u> </u>			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic							¦ 				
Fetal / Obstetrics[7]	Р	P	Р	<u> </u>	P	N	Р	Р	_ P _	Р	[6]
Abdominal ^[1]	Р	P_	P		Р	N	P	Р	P	Р_	[6]
Pediatric	Р_	Р	P		Р	N	P	P	Р_	P	[6]
Small Organ ^[2]				<u> </u>		ļ	ļ	ļ	<u> </u>		
Neonatal Cephalic			<u> </u>		ļ	ļ		 	ļ	<u> </u>	
Adult Cephalic							<u> </u>		<u> </u>	 	-
Cardiac ^[3]		ļ.—	ļ		ļ	<u> </u>	ļ	ļ.——			
Peripheral Vascular			<u> </u>	ļ		<u> </u>	ļ <u> </u>	ļ <u> </u>			
Musculo-skeletal Conventional	P	P	P	<u> </u>	P	N	P	Р	Р	P	[6]
Musculo-skeletal Superficial				<u> </u>	<u> </u>	-	<u> </u>			<u> </u>	
Other		<u> </u>		<u> </u>	<u> </u>	ļ	 -			ļ	╂
Exam Type, Means of Access		ļ		<u> </u>	ļ				ļ. <u> </u>	 	
Transesophageal		ļ		<u> </u>	ļ	 	 		ļ <u>-</u>	 	
Transrectal		ļ		<u> </u>	 	 			-	-	-
Transvaginal		<u> </u>		ļ		<u> </u>	<u> </u>	ļ			-
Transuretheral		<u> </u>	ļ		<u> </u>	ļ	-	-	 	 	
Intraoperative		-		 	 	 	_		 	 	-
Intraoperative Neurological		<u> </u>			 -		 		 	-	┨──
Intravascular				 	 		 	1	-	-	-
Laparoscopic		<u> </u>		<u></u>	<u> </u>	<u> </u>	- di., C	<u> </u>	<u></u>	<u>l</u>	<u>1</u>

Laparoscopic		<u> </u>	اا			<u> </u>	<u></u>	<u> </u>	 	
N = new indication; P = prev	riously cleared	by FDA; E	E = add	ed unde	r Apper	ndix E				
Notes: [1] Abdominal includes [6] Includes imaging [7] Includes infertility [*] Combined modes	of guidance of which was a substitution of the	biopsy (2 follicle dev	velopme	ent CWD, E	3/Color/	PWD or	CWD, B/	'Power/P	WD.	
	PLEASE DO NOT WRI									
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Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with AC2-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P_		P	N	P_	P_	Р	P	[6]
Abdominal ^[1]	Р_	Р	P	<u> </u>	P	N	Р_	P	P	_Р	[6]
Pediatric						<u> </u>		ļ	<u> </u>		
Small Organ ^[2]			<u> </u>			ļ			 		
Neonatal Cephalic		ļ	<u> </u>			<u> </u>		<u> </u>	<u> </u>		
Adult Cephalic			<u> </u>		ļ	ļ			 	ļ	
Cardiac ^[3]				ļ		<u> </u>		1	 		
Peripheral Vascular		ļ		ļ		<u> </u>			_	<u> </u>	
Musculo-skeletal Conventional		<u> </u>		ļ <u>.</u>	<u> </u>	<u> </u>	ļ	ļ			
Musculo-skeletal Superficial		<u> </u>	ļ <u>.</u>	<u> </u>	ļ		<u> </u>	ļ <u>-</u>			
Other		<u> </u>		<u> </u>	<u> </u>	-	ļ	<u> </u>			
Exam Type, Means of Access	_	<u> </u>		<u> </u>			 	<u> </u>	ļ. <u> </u>	ļ	
Transesophageal			ļ <u>-</u>	<u> </u>	<u> </u>	ļ	 -		 		
Transrectal			<u> </u>	<u> </u>		-	-		 	} -	<u> </u>
Transvaginal				-	 	 	-	-	 	 	- -
Transuretheral						<u> </u>	ļ		 	 	
Intraoperative			_			ļ	 -		 	 	-
Intraoperative Neurological		ļ		 	-	 -		1	1	 	
Intravascular				ļ		 	 	 	ļ	1-	
Laparoscopic		<u> </u>		<u> </u>	<u> </u>	<u></u>	<u> </u>		<u> </u>	<u></u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E Notes: [1] Abdominal includes renal, GYN/Pelvic [6] Includes imaging of guidance of biopsy (2D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[] Combined modes are binn, bicolor in, bit with or otto, bicolor in the control of otto, bic
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number __

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with SP4-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal ^[1]			<u> </u>								_
Pediatric	Р	P	P		P	N_	P	P	Р	P	[6]
Small Organ ^[2]	Р	P	Р_		Р	N	Р	Р	Р	Р	[6]
Neonatal Cephalic				<u></u>	-	ļ		ļ	ļ	· -	
Adult Cephalic				ļ							<u> </u>
Cardiac ^[3]			ļ							<u> </u>	ļ
Peripheral Vascular	Р	P	Р		P	N	P	P	P	Р	[6]
Musculo-skeletal Conventional	P	Р	Р		Р	N	P	P	P	Р	[6]
Musculo-skeletal Superficial				<u> </u>	ļ	ļ		<u> </u>			ļ
Other	<u> </u>		<u> </u>	ļ				<u> </u>			<u> </u>
Exam Type, Means of Access		ļ <u>-</u>		<u> </u>							
Transesophageal				ļ		ļ					
Transrectal		ļ		<u> </u>		ļ	ļ	1	ļ		
Transvaginal		ļ				 	ļ	ļ	ļ 		-
Transuretheral		<u> </u>				<u> </u>	<u> </u>		 	ļ <u> </u>	
Intraoperative		ļ <u> </u>			ļ <u>. </u>		ļ <u>.</u>		<u> </u>		-
Intraoperative Neurological		ļ	ļ	ļ	_	_	<u> </u>		<u> </u>	 	-
Intravascular		<u> </u>				<u> </u>	<u> </u>		ļ	_	╂
Laparoscopic N = new indication; P = pre						<u> </u>	<u></u>	<u> </u>		<u> </u>	<u> </u>

							T		1		1
Laparoscopic			<u> </u>	<u> </u>		ļ <u>.</u>	<u> </u>	<u> </u>	<u> </u>	l . <u></u>	
N = new indication; P = pr	eviously c	leared b	y FDA;	E = add	ded unde	er Apper	ndix E			_	
Notes: [2] Small organ in					vary glai	nd, lymp	h nodes,	pediatri	c and nec	natal pa	tients
[6] Includes imagi	ng of guid:	ance of	biopsy ((2D)							
[*] Combined mod	les are B/f	M, B/Co	lor M, B	/PWD o	CWD, I	3/Color/I	PWD or	CWD, B/	Power/P\	ND.	
• •											
							<u></u>				
	(PLEASE DO										
	Con	currence	e of CDR	H, Office	of Devi	ce Evalua	ation (OD	E)			

(Division Sign-Off) Division of Reproductive. Abdominal, and Radiological Devices 510(k) Number

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with SP6-12 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation													
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes			
Ophthalmic					<u> </u>						_			
Fetal / Obstetrics ^[7]								ļ						
Abdominal ^[1]											ļ			
Pediatric	Р	Р	Р		P	N	Р_	Р	_ P	P	[6]			
Small Organ ^[2]	P	Р	P	<u> </u>	Р	N	Р	Р	Р	Р	[6]			
Neonatal Cephalic			<u> </u>	ļ	ļ			<u> </u>	ļ		ļ. <u></u> -			
Adult Cephalic				ļ	ļ	<u> </u>		ļ			ļ			
Cardiac ^[3]				<u> </u>				ļ	ļ		ļ			
Peripheral Vascular	Р_	Р	P		P	N	P	Р	P	Р	[6]			
Musculo-skeletal Conventional	P	P_	P		P	N_	P.	Р	Р	P	[6]			
Musculo-skeletal Superficial	Р	Р	P	<u> </u>	Р	N	Р	Р	P	Р	[6]			
Other			_	<u> </u>		ļ	ļ	ļ			ļ .			
Exam Type, Means of Access		ļ					<u> </u>	ļ <u></u>		<u> </u>	ļ —			
Transesophageal								<u> </u>			ļ			
Transrectal				ļ						ļ	-			
Transvaginal				ļ		<u> </u>	ļ	1						
Transuretheral			<u> </u>			ļ		ļ	ļ		ļ			
Intraoperative				<u> </u>			1	<u> </u>			-			
Intraoperative Neurological				ļ	1			 			<u> </u>			
Intravascular				ļ. <u>.</u>				ļ			-			
Laparoscopic						<u> </u>	<u> </u>	<u> </u>	<u> </u>	1	<u> </u>			

Intravascular				 			ļ	 		 	
Laparoscopic		<u> </u>	<u> </u>			<u> </u>	<u> </u>	<u> </u>	<u></u>	<u>1</u>	<u> </u>
N = new indication; P =	previously	/ cleared	by FDA;	E = add	ded unde	er Apper	idix E				
Notes: [2] Small organ	includes t	reast, tes	stes, thy	oid, sali	vary glar	nd, lymp	h nodes,	pediatri	c and nee	onatal pa	atients
[6] Includes ima	iging of gu	idance of	biopsy	(2D)							
[*] Combined m	odes are	B/M, B/Cd	olor M, B	/PWD o	r CWD, E	3/Color/I	PWD or	CWD, B	Power/P	WD.	
										 	
	,	DO NOT WRI									
	C	oncurrenc	e of CDF	RH, Office	of Device	e Evalu	ation (OD	E)			

Division of Reproductive, Abdominal, and Radiological Devices

(Division Sign-Off)

510(k) Number ___

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with SP10-16 Transducer

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											
Fetal / Obstetrics ^[7]											_
Abdominal ⁽¹⁾											
Pediatric								ļ			
Small Organ ^[2]	Р	Р	P		P	N	Р.	Р	Р	P	[6]
Neonatal Cephalic											<u> </u>
Adult Cephalic											ļ
Cardiac ^[3]					ļ		<u></u>				ļ
Peripheral Vascular				ļ			ļ		<u> </u>		ļ
Musculo-skeletal Conventional									ļ		ļ
Musculo-skeletal Superficial	P	P	Р		Р	N	P	Р	P	Р	[6]
Other			ļ. <u>.</u>	<u> </u>	ļ			ļ			
Exam Type, Means of Access					<u> </u>						<u> </u>
Transesophageal		<u> </u>		<u> </u>		<u> </u>					
Transrectal				<u> </u>	ļ			<u> </u>			ļ
Transvaginal		<u> </u>		ļ	ļ		ļ				-
Transuretheral		<u> </u>		<u> </u>			ļ				<u> </u>
Intraoperative							 				ļ
Intraoperative Neurological		<u> </u>		<u> </u>	ļ			ļ .		ļ	-
Intravascular						ļ	ļ. 		ļ		
Laparoscopic	<u> </u>		<u> </u>	<u></u>	<u> </u>		<u> </u>	<u> </u>	1	<u> </u>	
N = new indication; P = prev Notes: [2] Small organ incli	viously	cleared	by FDA;	E = ad	ded unde	er Apper	ndix E	4: _ 4.4		- loton	ntiont

intravascular		 		<u> </u>		1				_	
Laparoscopic					<u> </u>		<u> </u>	<u> </u>			
V = new indication;	P = previously	cleared	y FDA;	E = add	ded unde	er Appen	dix E				
Notes: [2] Small org	jan includes b	reast, tes	tes, thyr	oid, sali	vary glar	id, lympl	n nodes,	pediatrio	and nec	natal pa	atients
[6] Includes	imaging of gui	dance of	biopsy ((2D)							
[*] Combine	d modes are E	8/M, B/Co	lor M, B	/PWD or	CWD, E	3/Color/F	PWD or 0	CWD, B/I	Power/PV	VD.	
1.7											
				-						-	
											
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	Co	ncurrenc	e of CDF	H, Office	of Devic	e Evalua	ition (OD	E)			

(Division Sign-Off)

510(k) Number ___

and Radiological Devices

(Division Sign-Off) ()
Division of Reproductive. Abdominal,

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with PA2-5P Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											
Fetal / Obstetrics ^[7]											-
Abdominal ^[1]	Р	Р	P	Р	Р	Р	Р	P	P	Р	<u> </u>
Pediatric			ļ					<u>-</u>			
Small Organ ^[2]			ļ			<u> </u>	 			ļ	
Neonatal Cephalic		ļ			-	ļ				ļ	
Adult Cephalic	Р	Р	P	Р	Р	P	P	Р	Р_	P	-
Cardiac ^[3]	Р	P	P	P	Р	Р	Р	Р	P	Р	.
Peripheral Vascular				ļ		<u> </u>				ļ	-
Musculo-skeletal Conventional						ļ. <u>.</u> .	ļ		ļ 		
Musculo-skeletal Superficial		<u> </u>		<u> </u>		ļ	ļ	ļ	ļ <u>.</u>	ļ	
Other ^[4]			<u> </u>	ļ	ļ	<u> </u>		<u> </u>	 		
Exam Type, Means of Access					<u> </u>		ļ <u>.</u> .		ļ	ļ	-
Transesophageal					ļ	ļ		<u> </u>			
Transrectal		ļ		 	 				ļ. <u></u>	 	
Transvaginal		<u> </u>	.	ļ	<u> </u>	 -				ļ .	
Transuretheral		<u> </u>	_	ļ	<u> </u>					 	
Intraoperative		ļ				ļ	<u> </u>	ļ	ļ	<u> </u>	 -
Intraoperative Neurological				<u> </u>	ļ	ļ	ļ			 	-
Intravascular		<u> </u>			1	 	<u> </u>	ļ		 	 -
Laparoscopic N = new indication; P = prev		<u>l</u>	<u> </u>			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Transrectal	I.								 	
Transvaginal			_		_				ļ <u>.</u>	
Transuretheral								ļ. <u></u> .	 	ļ
Intraoperative							ļ	ļ		ļ
Intraoperative Neurological						ļ	<u> </u>		_	<u> </u>
Intravascular							ļ <u>.</u>			ļ
Laparoscopic N = new indication; P = pre						<u> </u>			<u> </u>	<u> </u>
Notes: [1] Abdominal inclu [3] Cardiac is Adult [*] Combined mode	t and Pedi	iatric.		or CWD,	, B/Color	/PWD or	CWD, B/	/Power/P	WD.	
	(PLEASE DO	NOT WRITE B	ELOW THIS LIN	NE - CONTINU	E ON ANOT	HER PAGE IF	NEEDED)	 		
	Cond	currence o	f CDRH, Of	fice of Dev	rice Evalu	ation (O	DE)			
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Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with PA6-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											<u> </u>
Fetal / Obstetrics ^[7]			<u> </u>								ļ . -
Abdominal ^[1]								<u> </u>			
Pediatric		. <u> </u>	<u> </u>								ļ . <u> </u>
Small Organ ^[2]					<u> </u>					_	
Neonatal Cephalic	Р	Р	P	Р	Р	P	Р	P	Р	Р	
Adult Cephalic				ļ <u>.</u>	<u> </u>						ļ
Cardiac ^[3]	Р	Р	P	Р	Р	P	Р	Р	Р	Р_	-
Peripheral Vascular			<u> </u>		<u> </u>						
Musculo-skeletal Conventional				ļ	<u></u>						
Musculo-skeletal Superficial						ļ	ļ	<u> </u>			
Other ^[4]						ļ		ļ			<u> </u>
Exam Type, Means of Access			ļ	ļ. <u>.</u>	<u> </u>			<u> </u>			<u> </u>
Transesophageal			<u> </u>	ļ		<u> </u>		<u> </u>	ļ		<u> </u>
Transrectal					ļ <u>.</u>	ļ		ļ	ļ		
Transvaginal				<u> </u>			<u> </u>	<u> </u>	 		ļ
Transuretheral				ļ		ļ. <u> </u>	ļ <u></u>	ļ	<u> </u>	<u> </u>	ļ
Intraoperative				<u> </u>			ļ	ļ	ļ	-	1
Intraoperative Neurological					<u> </u>		ļ	<u> </u>	<u> </u>	ļ <u> </u>	ļ
Intravascular			<u> </u>	<u> </u>			<u> </u>				-
Laparoscopic N = new indication; P = pre		1	<u> </u>	<u> </u>	<u></u>		<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Transvaginal				<u> </u>	<u> </u>		
Transuretheral		<u> </u>					
Intraoperative							
Intraoperative Neurological					1		
Intravascular		<u> </u>					
Laparoscopic					_		<u>l</u>
N = new indication; P = pre Notes: [3] Cardiac is Adult [*] Combined mode	and Pediatric.				CWD, B/F	Power/PWD.	
(PLEASE DO NOT WRI	ITE BELOW THIS LIN	IE - CONTINUE ON AN	OTHER PAGE I	F NEEDED)		
	Concurrence	ce of CDRH, Of	fice of Device Ev	aluation (O	DE)		
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			Division (ot Heprod	uctive, Ai	bdominal,	1

Prescription User (Per 21 CFR 801.109)

and Radiological Devices

510(k) Number _

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with IC5-9 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

}	Mode of Operation												
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other {Notes		
Ophthalmic				ļ	<u></u>						ļ		
Fetal / Obstetrics[7]	Р	Р	Р		Р	N	Р	Р	Р	Р	[6]		
Abdominal ^[1]						ļ					<u> </u>		
Pediatric				<u></u>					ļ		ļ		
Small Organ ^[2]					ļ <u> </u>	<u> </u>				ļ	<u> </u>		
Neonatal Cephalic									ļ				
Adult Cephalic			ļ							ļ. <u>. </u>			
Cardiac ^[3]					ļ					ļ	 		
Peripheral Vascular				ļ		ļ		<u> </u>	ļ	<u></u>	ļ		
Musculo-skeletal Conventional													
Musculo-skeletal Superficial		<u></u>		ļ. <u>.</u>					ļ		_		
Other	<u></u> .			<u> </u>				ļ		ļ	ļ		
Exam Type, Means of Access					ļ <u>.</u>	ļ			<u> </u>		<u> </u>		
Transesophageal				<u> </u>	ļ. <u>.</u>			ļ			<u> </u>		
Transrectal	Р	P	P	<u> </u>	P	N	P	Р	Р_	Р	[6]		
Transvaginal	Р	Р	Р	ļ <u>.</u>	P	N	P	Р	Р	Р	[6]		
Transuretheral					ļ. <u>.</u>						ļ		
Intraoperative				ļ	 		ļ <u>.</u>		ļ		<u> </u>		
Intraoperative Neurological				<u> </u>		1	ļ			ļ	<u> </u>		
Intravascular					<u> </u>		<u> </u>		ļ	ļ	1		
Laparoscopic N = new indication; P = pro		<u> </u>	<u></u>	<u></u>			<u> </u>	<u> </u>		ļ <u>.</u>			

Laparoscopic				<u> </u>	<u> </u>						<u> </u>
N = new indication; P = pr	eviously	cleared	by FDA	; E = ac	ided und	ler Appe	ndix E				
Notes: [6] Includes imagic	ng of gui	dance o	f biopsy	(2D)							
[7] Includes infertil	lity moni	toring of	follicle (developr	nent						
[*] Combined mod	es are E	3/M, B/C	olor M, I	3/PWD d	or CWD,	B/Color	/PWD or	CWD, E	B/Power/F	PWD.	
			<u></u>								
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	Co	ncurren	ce of CD	RH, Offic	e of Dev	ice Evalu	uation (O	DE)			
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(Division Sign-Off)

510(k) Number ___

and Radiological Devices

Division of Reproductive, Abdominal,

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with SCW2.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation Node of Operation Node of Operation Node of Operation Node of Operation												
	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes		
Ophthalmic													
etal / Obstetrics ^[7]					ļ						ļ.—		
Abdominal ^[1]											_		
Pediatric			<u></u>										
Small Organ ^[2]			<u> </u>			<u> </u>				ļ	_		
Neonatal Cephalic		<u> </u>	<u> </u>		,						 		
Adult Cephalic			<u> </u>							ļ			
Cardiac ^[3]				Р	<u> </u>						ļ		
Peripheral Vascular					ļ	ļ		<u> </u>		<u> </u>			
Musculo-skeletal Conventional			<u> </u>	<u> </u>	ļ	ļ				ļ	<u> </u>		
Musculo-skeletal Superficial				ļ		ļ				ļ	ļ		
Other ^[4]		<u> </u>			<u> </u>	<u> </u>				ļ			
Exam Type, Means of Access				<u> </u>	<u> </u>			ļ. <u>.</u>	_	_	<u> </u>		
Transesophageal	<u>.</u>	<u> </u>		ļ		ļ		<u>_</u>		ļ	 		
Transrectal				ļ		ļ	ļ	ļ <u>-</u>			ļ		
Transvaginal		<u> </u>				ļ		<u> </u>	<u> </u>	<u> </u>	ļ		
Transuretheral				ļ					ļ . <u>-</u> -	ļ	ļ . <u></u>		
Intraoperative				<u> </u>			ļ	<u> </u>		<u> </u>	ļ <u> </u>		
Intraoperative Neurological				<u> </u>				ļ	<u> </u>	ļ	<u> </u>		
Intravascular					ļ	<u> </u>		<u> </u>	ļ <u></u>	<u> </u>			
Laparoscopic I = new indication; P = prev			<u> </u>	<u></u>	<u> </u>	<u></u>		<u> </u>	<u>i</u>	<u> </u>	<u> </u>		

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with PCW4.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											
Fetal / Obstetrics ^[7]					ļ						<u> </u>
Abdominal ^[1]								<u></u>			ļ
Pediatric					ļ <u> </u>						
Small Organ ^[2]			<u> </u>							-	ļ
Neonatal Cephalic		<u></u>				ļ					ļ
Adult Cephalic								<u> </u>			
Cardiac ^[3]				Р				ļ			ļ
Peripheral Vascular				Р							ļ
Musculo-skeletal Conventional			1		ļ <u>. </u>						<u> </u>
Musculo-skeletal Superficial		<u> </u>									
Other ^[4]		<u> </u>	ļ						<u> </u>		
Exam Type, Means of Access					ļ. <u> </u>	ļ					1
Transesophageal								<u> </u>			
Transrectal				ļ				ļ	ļ		
Transvaginal						ļ		<u> </u>			
Transuretheral		<u>.</u>									
Intraoperative		<u> </u>		<u> </u>			ļ	ļ			
Intraoperative Neurological			<u> </u>	<u> </u>				<u> </u>	ļ		
Intravascular		<u> </u>	<u> </u>			<u>.</u>		ļ <u>.</u>			
Laparoscopic				1					1]	<u> </u>

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number ____

Special 510(k) Premarket Notification GE Voluson 730 Expert/Pro BT04 Ultrasound June 18, 2004

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RAB2-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

İ					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic					ļ			<u> </u>			<u> </u>
Fetal / Obstetrics[7]	Р	Р	Р		P	N	Р	Р	Р	P	[5,6]
Abdominal ^[1]	Р	P	P		P	N	P	P	Р	Р	[5,6]
Pediatric			ļ				ļ			-	
Small Organ ^[2]			<u> </u>		ļ						
Neonatal Cephalic			<u> </u>			ļ <u> </u>	-				
Adult Cephalic			ļ		ļ.,,,,,		ļ <u>-</u> -				
Cardiac ^[3]			<u> </u>		<u> </u>	ļ				 	
Peripheral Vascular		ļ			<u> </u>	ļ		-	ļ		ļ
Musculo-skeletal Conventional	Р	Р	P		P	N	Р	P	Р	P	[5,6]
Musculo-skeletal Superficial		ļ	<u> </u>		<u> </u>	<u> </u>				 	 -
Other			<u> </u>	<u> </u>	ļ		ļ <u>.</u>		ļ	ļ	
Exam Type, Means of Access				ļ		 -	<u> </u>				
Transesophageal			<u> </u>		.	 -		 		ļ	
Transrectal	- -		-	<u> </u>		ļ	ļ	<u> </u>		ļ	
Transvaginal					<u> </u>			ļ. <u>.</u>			
Transuretheral		ļ	ļ. <u>.</u>	ļ	-		 	 	ļ		-
Intraoperative		-	<u> </u>	ļ		<u> </u>	<u> </u>	 -		-	-
Intraoperative Neurological		ļ . <u> </u>			-	-	ļ	<u> </u>		1	
Intravascular					ļ	-	 -	ļ	 	ļ	-
Laparoscopic				<u> </u>		<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[1] Abdominal includes renal, GYN/Pelvic	
	[5] 3D/4D Imaging Mode	

- [6] Includes imaging of guidance of biopsy (3D/4D)
- [7] Includes infertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RAB4-8P Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	ir.	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes)	
Ophthalmic											ļ	
Fetal / Obstetrics[7]	_ P	Р	P	<u> </u>	Р	N	Р	Р	Р	Р	[5,6]	
Abdominal ^[1]	Р_	Р	P		Р	N	Р	Р	P	Р	[5,6]	
Pediatric			ļ. <u></u> .	}		ļ						
Small Organ ^[2]			<u> </u>			<u> </u>					<u> </u>	
Neonatal Cephalic											 	
Adult Cephalic						ļ	ļ		ļ		ļ. <u> </u>	
Cardiac ^[3]			<u></u>								<u> </u>	
Peripheral Vascular				<u></u>					_	ļ 	↓	
Musculo-skeletal Conventional	Р	P_	P	<u> </u>	Р	N	Р	P	P	Р	[5,6]	
Musculo-skeletal Superficial			ļ <u>.</u>	<u> </u>	ļ							
Other					ļ			1			 -	
Exam Type, Means of Access		<u></u>	<u> </u>	ļ					<u> </u>			
Transesophageal			ļ			ļ	<u> </u>	ļ			—	
Transrectal			ļ <u>.</u>	<u> </u>	<u> </u>		ļ <u>.</u>		ļ		 -	
Transvaginal		ļ	ļ	ļ	<u> </u>	ļ					ļ	
Transuretheral		<u> </u>		ļ	1	<u> </u>					ļ <u></u> -	
Intraoperative		ļ		ļ	<u> </u>						 	
Intraoperative Neurological					<u> </u>						—	
Intravascular					<u> </u>	<u> </u>	 	-	-		 	
Laparoscopic	l	<u></u>	<u> </u>	<u></u>	<u> </u>		<u> </u>	1	<u> </u>	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

[6] Includes imaging of guidance of biopsy (3D/4D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number

Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RAB2-5L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes	
Ophthalmic			<u> </u>								ļ	
Fetal / Obstetrics[7]	Р	Р	Р		Р	N	P	P_	Р	Р	[5,6]	
Abdominal ^[1]	P	Р_	P		P	N	Р_	Р	P_	Р_	[5,6]	
Pediatric												
Small Organ ^[2]				ļ <u></u>							ļ <u> </u>	
Neonatal Cephalic				ļ		ļ <u>-</u>	<u> </u>					
Adult Cephalic			<u> </u>		_	<u> </u>	ļ				<u> </u>	
Cardiac ^[3]				ļ					<u> </u>		 	
Peripheral Vascular				<u> </u>				<u> </u>			<u> </u>	
Musculo-skeletal Conventional	Р	P	P	ļ	P	N	P	Р	P	P	[5,6]	
Musculo-skeletal Superficial		<u> </u>	ļ			<u> </u>	<u> </u>	<u> </u>			 _	
Other					ļ		ļ				<u> </u>	
Exam Type, Means of Access		<u> </u>	ļ	ļ		ļ	ļ		<u> </u>		<u> </u>	
Transesophageal		ļ	<u> </u>			ļ		-			<u> </u>	
Transrectal		ļ			ļ		<u> </u>			ļ	-	
Transvaginal		<u> </u>		1	ļ			<u> </u>	ļ. <u>.</u>		 	
Transuretheral		<u> </u>	<u> </u>		-				 -	-	-	
Intraoperative		ļ		ļ .	ļ		 	 		 	+	
Intraoperative Neurological			_	ļ	ļ		ļ	ļ <u> </u>	<u> </u>		-	
Intravascular		<u> </u>		<u> </u>		-			ļ	 	 	
Laparoscopic				<u> 1</u>	<u>.l</u>		<u> </u>	<u> </u>	<u> </u>		<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E Notes: [1] Abdominal includes renal, GYN/Pelvic

1	51	3D/4D	Imaging	Mode
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- [6] Includes imaging of guidance of biopsy (3D/4D)
- [7] Includes infertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RAB4-8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes)	
Ophthalmic			J									
Fetal / Obstetrics ^[7]	Р	Р	Р		Р_	N_	Р	P	Р	Р	[5,6]	
Abdominal ^[1]	Р	P	P		Р	N	P	P	P	Р	[5,6]	
Pediatric				ļ <u> </u>	ļ	ļ					ļ	
Small Organ ^[2]			ļ			ļ						
Neonatal Cephalic			<u> </u>		ļ						 	
Adult Cephalic			<u> </u>					ļ . <u>-</u>		<u> </u>		
Cardiac ^[3]			ļ		<u> </u>	ļ	<u> </u>				}	
Peripheral Vascular		ļ				ļ	ļ			<u> </u>	 	
Musculo-skeletal Conventional	Р	P	P	ļ	Р	N	Р	P	P_	P	[5,6]	
Musculo-skeletal Superficial		ļ		<u> </u>	<u></u>	ļ		 		ļ	ļ	
Other		<u> </u>	<u> </u>	ļ		<u> </u>	ļ	<u> </u>	ļ. 	ļ	-	
Exam Type, Means of Access		<u> </u>	<u> </u>		 			 		 	-	
Transesophageal		<u> </u>		<u> </u>				ļ		<u> </u>	 -	
Transrectal			<u> </u>	ļ	. 	<u> </u>		<u> </u>	 	 	-	
Transvaginal			<u> </u>	<u> </u>	 	ļ	 	 	 	ļ 		
Transuretheral			<u> </u>	<u> </u>			<u> </u>	 			┼	
Intraoperative		<u> </u>		ļ <u>.</u>		-	<u> </u>	 	<u> </u>	 	-	
Intraoperative Neurological		ļ	_				 	-	_	-	-	
Intravascular		<u> </u>		 -		<u> </u>		ļ. <u>.</u> .	ļ			
Laparoscopic		<u> </u>	<u> </u>	<u></u>	<u></u>			<u> </u>	<u> </u>	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

[6] Includes imaging of guidance of biopsy (3D/4D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RSP5-12 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application Anatomy/Region of Interest	₿	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes		
Ophthalmic											ļ		
Fetal / Obstetrics ^[7]							ļ			. <u></u>	 		
Abdominal ^[1]						ļ <u>-</u>					 		
Pediatric	Р	Р	Р	ļ	Р	N	P	Р	Р_	_ P	[5,6]		
Small Organ ^[2]	Р	P	P		Р	N	P	P_	Р	P	[5,6]		
Neonatal Cephalic			<u> </u>		ļ	<u> </u>	ļ		. 		 		
Adult Cephalic				ļ <u>. </u>							 		
Cardiac ^[3]					ļ				ļ		 		
Peripheral Vascular	Р	Р	Р	ļ	P	N	Р	P	P	P	[5,6]		
Musculo-skeletal Conventional		<u> </u>				ļ	ļ			<u> </u>	 		
Musculo-skeletal Superficial	Р	P	Р		P	N	P	P	Р	Р	[5,6]		
Other		<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>		-			-		
Exam Type, Means of Access		<u> </u>		<u> </u>	<u> </u>	<u> </u>			<u> </u>		├- -		
Transesophageal		ļ			<u> </u>		<u> </u>	<u> </u>	 		-		
Transrectal			<u> </u>		<u> </u>	<u> </u>	<u> </u>				-		
Transvaginal		<u> </u>		 	 			ļ	<u> </u>	-	╂		
Transuretheral		ļ					<u> </u>		<u> </u>	 	 		
Intraoperative	Р	P_	P	ļ	P	N	P	P	P	P	 		
Intraoperative Neurological	P	P	Р		P	N	P	Р	P	P	+		
Intravascular		<u> </u>			 	 -	 		 	 	 -		
Laparoscopic				<u> </u>		<u> </u>	<u> </u>			<u> </u>	<u></u>		

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	oscopic	<u> </u>	<u> </u>		<u> </u>	<u> </u>	<u> </u>			<u> </u>	
N = ne	w indication; P = pre	eviously clea	ared by FD	A; E = ac	ded und	er Apper	ndix E				
Notes:	[2] Small organ inc	ludes breas	st, testes, th	yroid, sa	livary gla	nd, lympi	h nodes	pediatri	and ned	onatal pa	ıtients
	[5] 3D/4D Imaging	Mode									
	[6] Includes imagin	g of guidan	ce of biops	y (3D/4D))						
	[7] Includes infertili	ty monitorin	ng of follicle	develop	ment						
	[*] Combined mode	es are B/M,	B/Color M,	B/PWD (or CWD, i	B/Color/I	PWD or	CWD, B/	Power/P\	ND.	
	• •										
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and Radiological Devices 510(k) Number

(Division Sign-Off)

Division of Reproductive. Abdominal,

Diagnostic Ultrasound Indications for Use Form GE Voluson 730Pro/Expert with RIC5-9 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]		
Ophthalmic											<u> </u>		
Fetal / Obstetrics[7]	P	Р	Р		Р	N	Р	Р	Р	P	[5,6]		
Abdominal ^[1]			ļ		<u> </u>	ļ							
Pediatric					ļ	 	ļ <u> </u>				├		
Small Organ ^[2]		_	_ 		ļ <u>.</u>	_	ļ		·	<u> </u>			
Neonatal Cephalic			<u> </u>		<u> </u>		<u> </u>				-		
Adult Cephalic					<u> </u>						<u> </u>		
Cardiac ^[3]		ļ	ļ		ļ	ļ		ļ			ļ		
Peripheral Vascular		<u> </u>		<u> </u>	<u> </u>		ļ	<u> </u>			<u> </u>		
Musculo-skeletal Conventional			<u> </u>	ļ	<u> </u>	ļ		<u> </u>	ļ		ļ		
Musculo-skeletal Superficial			<u> </u>	ļ	ļ	ļ		ļ	 				
Other		ļ	_	<u> </u>	ļ		ļ	ļ			-		
Exam Type, Means of Access				<u> </u>	ļ <u>.</u>			. 	ļ	 	 		
Transesophageal		<u> </u>			<u> </u>	ļ		<u> </u>			 		
Transrectal	Р	P	P		Р	N	P	P	P	P	[5,6]		
Transvaginal	Р	Р	P	ļ	Р	N	P	P	Р	P	[5,6]		
Transuretheral				<u> </u>		_					-		
Intraoperative		 		<u> </u>	ļ	ļ. <u></u>	<u> </u>	<u> </u>		 	-		
Intraoperative Neurological		ļ	_	-	ļ			<u> </u>	<u> </u>	 			
Intravascular		<u> </u>	 	<u> </u>	 	1	<u> </u>	 _	 	-	-		
Laparoscopic		<u> </u>				<u> </u>	ماند ٦	<u> </u>		<u> </u>	<u> </u>		

Laparooopio	
= new indication; P = pre	viously cleared by FDA; E = added under Appendix E
[7] Includes infertili	Mode g of guidance of biopsy (3D/4D) ty monitoring of follicle development as are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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	Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive. Abdominal, and Radiological Devices 530(k) Number __

Special 510(k) Premarket Notification GE Voluson 730 Expert/Pro BT04 Ultrasound June 18, 2004

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RRE6-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes	
Ophthalmic					_							
Fetal / Obstetrics ^[7]												
Abdominal ^[1]			1									
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic			ļ . <u>.</u>									
Adult Cephalic				<u> </u>							ļ	
Cardiac ^[3]				<u> </u>								
Peripheral Vascular								ļ			ļ	
Musculo-skeletal Conventional												
Musculo-skeletal Superficial											ļ	
Other											<u> </u>	
Exam Type, Means of Access			<u> </u>	L .					ļ			
Transesophageal											<u> </u>	
Transrectal	Р	P	Р		Р	N	P	P	Р	P	[5,6]	
Transvaginal	-				_							
Transuretheral				<u> </u>							ļ	
Intraoperative								ļ <u> </u>			ļ	
Intraoperative Neurological			<u> </u>	<u> </u>				ļ	<u> </u>			
Intravascular			<u> </u>	ļ				ļ			<u> </u>	
Laparoscopic N = new indication; P = prev									<u> </u>		<u> </u>	

II III U V U SOUIUI	 	- <u>'</u>				}		1	
Laparoscopic		<u> </u>		<u> </u>			<u> </u>	<u> </u>	<u>L</u>
N = new indication; P = pre	viously cleared	by FDA; $E = a$	dded unde	er Apper	ndix E				
Notes: [5] 3D/4D Imaging	Mode								
[6] Includes imagin	g of guidance of	i biopsy (3D/4D)						
[*] Combined mode	s are B/M, B/Co	olor M, B/PWD	or CWD, E	3/Color/I	PWD or	CWD, B/	Power/P\	ND.	
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		<u> </u>							
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	Concurrence	e of CDRH, Offi	ce of Devic	e Evalua	ation (OD	E)			_
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510(k) Number ____

and Radiological Devices

Division of Reproductive. Abdominal,

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with 4C-A Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]		
Ophthalmic			ļ								 		
Fetal / Obstetrics[7]	_ N	N	N		N	N	N	N	N	N	[6]		
Abdominal ^[1]	_ N	N	N		N	N	N	N_	N_	N	[6]		
Pediatric			<u> </u>								 		
Small Organ ^[2]			<u>.</u>	ļ <u> </u>		ļ	ļ	<u> </u>	<u> </u>		 		
Neonatal Cephalic					ļ	-		ļ	<u> </u>		 		
Adult Cephalic								ļ			 		
Cardiac ^[3]			_					ļ			 -		
Peripheral Vascular	N	N	N	ļ	N	N	N	N	N_	N	[6]		
Musculo-skeletal Conventional		ļ	_			<u> </u>		<u> </u>	<u></u>	·-	 		
Musculo-skeletal Superficial		<u> </u>						ļ		-	1		
Other		<u> </u>	_	ļ <u>.</u>	<u> </u>	ļ		<u> </u>	ļ	<u> </u>	 		
Exam Type, Means of Access		ļ				<u> </u>		<u> </u>			 		
Transesophageal				<u> </u>		ļ	-			<u></u>	 		
Transrectal		<u> </u>		ļ	ļ		ļ	-	1	ļ <u>.</u>	 		
Transvaginal	<u>., </u>	 		ļ	ļ			-	 		├		
Transuretheral			<u> </u>	<u> </u>		<u> </u>	ļ <u> </u>	ļ					
Intraoperative		 	<u> </u>	ļ		ļ	ļ	ļ			_		
Intraoperative Neurological		<u> </u>	_	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>	ļ	 		
Intravascular				<u> </u>	ļ. <u>.</u>	ļ	ļ		ļ . <u>-</u>				
Laparoscopic				1	J	<u> </u>	<u> </u>	<u>, </u>	<u> </u>	1	<u></u>		

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [1] Abdominal includes renal, GYN/Pelvic
[6] Includes imaging of guidance of biopsy (2D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _

Diagnostic Ultrasound Indications for Use Form GE Voluson 730Pro/Expert with RIC5-9H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											-
Fetal / Obstetrics ^[7]	N	N	N		N	N	N	N	N	N	[5,6]
Abdominal ^[1]			<u> </u>				ļ		<u> </u>		ļ <u> </u>
Pediatric					ļ		ļ				ļ
Small Organ ^[2]				ļ					<u> </u>		ļ
Neonatal Cephalic						ļ					<u> </u>
Adult Cephalic		<u></u>	ļ					ļ			ļ
Cardiac ^[3]		ļ	<u> </u>			ļ <u> </u>			 	ļ - -	
Peripheral Vascular			<u> </u>		<u> </u>	<u> </u>	<u> </u>		-	ļ	
Musculo-skeletal Conventional		ļ		ļ		ļ	ļ	ļ 	ļ <u></u>	<u> </u>	<u> </u>
Musculo-skeletal Superficial				ļ	ļ	ļ			ļ	<u> </u>	-
Other		<u> </u>		ļ	ļ	<u> </u>		-	 		-
Exam Type, Means of Access			<u> </u>	ļ	ļ		ļ	ļ	<u> </u>		-
Transesophageal			_	<u> </u>					<u> </u>		
Transrectal	N	N.	N		N	N	N	N	N N	N	[5,6]
Transvaginal	N	<u>, N</u>	N	ļ	N	N	N	N	N	N	[5,6]
Transuretheral				ļ	-	ļ <u>. </u>		-	 	-	
Intraoperative				 - -		-		 -	ļ		
Intraoperative Neurological		<u> </u>		 	 		<u> </u>	<u> </u>	-	-	
Intravascular		<u> </u>				ļ	.	<u> </u>		ļ	-
Laparoscopic		<u> </u>	1	1			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

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Laparoscopic			<u> </u>	<u></u>			<u> </u>		<u> </u>	<u>L</u>	<u> </u>
l = new indication; P = pre	viously o	cleared b	y FDA;	E = adc	ded unde	r Appen	dix E				
Notes: [5] 3D/4D Imaging I	Vlode										
[6] Includes imaging	g of guid	lance of	biopsy ((3D/4D)							
[7] Includes infertilit	y monito	oring of f	ollicle d	evelopm	ent						
[*] Combined mode	s are B/	M, B/Co	lor M, B	/PWD or	CWD, E	3/Color/F	PWD or I	CWD, B/	Power/P\	VD.	
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510(k) Number

Division of Reproductive, Abdominal, and Radiological Devices 1//()//

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with IC5-9H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic								<u> </u>			ļ
Fetal / Obstetrics[7]	N_	N	N		N	N	N	N	N	N	[6]
Abdominal ^[1]				<u> </u>			ļ . <u></u>		<u> </u>		
Pediatric	<u>,</u>	<u> </u>	<u> </u>		ļ						
Small Organ ^[2]							<u> </u>		<u> </u>	-	
Neonatal Cephalic						ļ. <u> </u>	ļ	ļ			<u> </u>
Adult Cephalic				ļ. <u>.</u>			<u> </u>				
Cardiac ^[3]		<u> </u>	<u>. </u>	ļ	ļ		<u> </u>				
Peripheral Vascular		<u> </u>	<u> </u>				ļ		ļ		
Musculo-skeletal Conventional	_	ļ	_	ļ	<u> </u>				ļ <u></u>		
Musculo-skeletal Superficial		<u> </u>	<u> </u>		<u> </u>						
Other		<u> </u>			<u> </u>		ļ	<u> </u>	<u> </u>		 - -
Exam Type, Means of Access		<u> </u>			ļ	ļ	ļ	ļ			<u> </u>
Transesophageal			ļ				<u> </u>		ļ		╁
Transrectal	<u>N</u>	N	N	ļ	N	N	N	N	N	N N	[6]
Transvaginal	N	N	N		N	N	N	N	N	N	[6]
Transuretheral			<u> </u>		ļ	ļ	<u> </u>	<u> </u>	<u> </u>		
Intraoperative		<u> </u>						ļ	 	-	
Intraoperative Neurological		ļ	_		<u> </u>		ļ	ļ		}	 -
Intravascular					<u> </u>	<u></u>		 	 	<u> </u>	╂
Laparoscopic				l	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>

Laparoscopic	<u></u>			<u> </u>		<u> </u>				<u> </u>
N = new indication, P = pr	eviously clea	red by FDA	E = ac	dded und	ler Appe	endix E				
Notes: [6] Includes imagir										
[7] Includes infertil	ity monitoring	g of follicle	develop	nent						
[*] Combined mod	es are B/M, I	3/Color M,	B/PWD (or CWD,	B/Color.	/PWD or	CWD, E	J/Power/F	PWD.	
<u></u>			<u> </u>						• • • •	
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	Concur	rence of CD	RH, Offic	ce of Dev	ice Evalu	uation (O	DE)			

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices KO4/686

Diagnostic Ultrasound Indications for Use Form GE Voluson 730 Pro/Expert with RNA5-9 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic				ļ							ļ. -
Fetal / Obstetrics ^[7]			<u> </u>			ļ					_
Abdominal ^[1]	N	N	N	ļ	N	N	N	N	N	N	[5,6]
Pediatric	N	N	N	<u>.</u>	N_	N	N	N	N	N	[5,6]
Small Organ ^[2]	N	N	N		N_	N	N	N .	N .	N	[5,6]
Neonatal Cephalic	N	N	N		N	N	N	N_	N	N.	[5]
Adult Cephalic	_							-		ļ	ļ
Cardiac ^[3]	N	N	N		N	N	N	N	N	N	[5]
Peripheral Vascular	N	N	N_	<u> </u>	N	N	N	N_	N	N_	[5,6]
Musculo-skeletal Conventional	N_	N	N	ļ	N	N	N	N	N	N	[5,6]
Musculo-skeletal Superficial			_					-	<u> </u>		<u> </u>
Other				<u> </u>	ļ	ļ				ļ .	
Exam Type, Means of Access		<u> </u>		ļ	. <u>.</u>	ļ		<u> </u>	<u> </u>	 	-
Transesophageal			<u> </u>	<u> </u>	<u> </u>			 -	-	ļ	-
Transrectal		ļ		<u> </u>		<u> </u>		-	 		
Transvaginal		ļ		ļ	ļ	ļ	1	<u> </u>			
Transuretheral		1	<u> </u>	 		<u> </u>	<u> </u>		 	-	-
Intraoperative	-	<u> </u>		<u> </u>			-	-	<u> </u>		
Intraoperative Neurological	·			<u> </u>	ļ	-		1	-	 	<u> </u>
Intravascular		ļ				 	1	<u> </u>	<u> </u>	 	 -
Laparoscopic		<u> </u>		<u> </u>		<u> </u>	.	<u> </u>	<u> </u>	<u> </u>	<u> 1</u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[1] Abdominal is Neonatal and Pediatric
	[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
	[3] Cardiac is Neonatal and Pediatric.

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Division of Reproductive, Abdominal,

and Radiological Devices 510k) Number